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### **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on April 14, 2008 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

#### ***Status of the Claims***

2. Claims 22, 24 and 33-45 are pending.

Applicants' amendment filed April 14, 2008 is acknowledged. Applicants' response has been fully considered. Claims 22 and 24 have been amended, claims 1, 7, 17-21, 23, 25, 26 and 30 have been cancelled, and new claims 38-45 have been added. Therefore, claims 22, 24 and 33-45 are examined.

#### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 22-24 and 33-37 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 5-7 in the amendment filed April 14, 2008.

#### ***Examiner's Amendment***

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

#### **Examiner's Amendments to the Specification:**

Please replace the paragraph amended at page 2 of the preliminary amendment filed January 27, 2004 with the following paragraph:

#### **CROSS-REFERENCE TO RELATED APPLICATIONS**

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This application claims is a divisional application of U.S. Application Serial No. 09/546,136, filed on April 10, 2000, now U.S. Patent 6,699,966, which is a continuation of U.S. Application Serial No. 08/889,354, filed on July 8, 1997, now abandoned, which claims the benefit of priority from U.S. Provisional Application Serial No. 60/021,348, filed on July 8, 1996, which are all incorporated herein by reference in their entirety.

**The following is an Examiner's Statement of Reasons for Allowance:** The state of art has disclosed the use of botulinum toxin in the treatment of a number of neuromuscular disorders involving muscular spasm and muscle injuries, e.g., Aoki et al., U.S. Patents 6,290,961, 6,319,505 and 6,423,319. However, the art does not teach or suggest the use of a polypeptide complex comprising a clostridium botulinum toxin and one or more clostridium botulinum type E neurotoxin associated polypeptides selected from the group consisting of a polypeptide comprising the amino acid sequence of SEQ ID NO:4, a polypeptide comprising the amino acid sequence of SEQ ID NO:3, a polypeptide comprising the amino acid sequence of SEQ ID NO:2, a polypeptide comprising the amino acid sequence of SEQ ID NO: 1, and a polypeptide comprising the amino acid sequence of SEQ ID NO:5, in the treatment disorders of undesirable muscle contraction due to exaggerated release of acetylcholine from presynaptic nerve terminals. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

May 17, 2008